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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,276

08/22/2005

Robyn O'Hehir

JKI-003USRCE

9537

959 7590 06/22/2010

LAHIVE & COCKFIELD, LLP  
FLOOR 30, SUITE 3000  
ONE POST OFFICE SQUARE  
BOSTON, MA 02109

EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

06/22/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,276	<b>Applicant(s)</b> O'HEHIR ET AL.	
	<b>Examiner</b> NORA M. ROONEY	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19,39,40,45-48 and 53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19,39,40,45,48 and 53 is/are allowed.
- 6) ☒ Claim(s) 46 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/09/2010 has been entered.

2. Claims 19, 39-40, 45-48 and 53 are pending.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 46-47 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a method of detecting hypersensitivity to a grass pollen of the subfamily Pooideae in a mammal, comprising measuring Lol p 5 T cell proliferation and IL-5 and IFN- $\gamma$  production induced by the peptides of SEQ ID NOs 33, 45, 46 and 53-54 wherein an increase in T cell proliferation and IL-5 and IFN- $\gamma$  production indicates the presence of hypersensitivity to said grass pollen, does not provide reasonable enablement for: a method of diagnosing or monitoring a hypersensitivity to a grass pollen of the subfamily Pooideae in a mammal said method comprising the steps of (a) obtaining T cells, IL-5 or IFN- $\gamma$  from the mammal, (b) **contacting said T cells, IL-5 or IFN- $\gamma$  with the peptides according to claim 19**

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**(c) measuring the amount of Lol p 5 reactive T cell proliferation, IL-5, or IFN- $\gamma$  production before and after step (b), and (d) comparing the amount of Lol p 5 reactive T cell proliferation, IL-5, or IFN- $\gamma$  production before and after step (b), wherein an increase in T cell proliferation, IL-5, or IFN- $\gamma$  production indicates the presence or increase of hypersensitivity to said grass pollen** of claim 46 and as applied to claim 47. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

Applicant's argument that they respectfully disagree, but have amended claim 46 to expedite prosecution thereby making this rejection moot filed on 06/09/2010 has been fully considered, but is not found persuasive.

It is the Examiner's position that the specification discloses on pages 52-57 that T cell proliferation and IL-5 and IFN- $\gamma$  production induced by the peptides of SEQ ID NOs 33, 45, 46 and 53-54 indicates the presence of hypersensitivity to said grass pollen. The specification does not adequately disclose a method of contacting the peptides with IL-5, or IFN- $\gamma$ , measuring the amount of Lol p 5 reactive T cell proliferation, IL-5, or IFN- $\gamma$  production and comparing the amount of Lol p 5 reactive T cell proliferation, IL-5, or IFN- $\gamma$  production wherein an increase in T cell proliferation, IL-5, or IFN- $\gamma$  production indicates the presence or increase of hypersensitivity to said grass pollen. The specification does not disclose nor does the art recognize a method whereby peptides can be contacted with IL-5, or IFN- $\gamma$  to elicit T cell proliferation, IL-5, or IFN- $\gamma$  production. Cells are required for the production of cytokines and the induction of T cell proliferation, though the claims read on contacting the peptides with the cytokines without the presence of any cells.

Therefore, the rejection is maintained.

13. Claims 19, 39-40, 45, 48 and 53 are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 18, 2010

Nora M. Rooney

Patent Examiner

Technology Center 1600

/Nora M Rooney/

Examiner, Art Unit 1644